

SAFETY DATA SHEET

Preparation Date: 3/09/2016

Revision Date: 6/19/2018

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: I2662
Product Name: ITRACONAZOLE, MICRONIZED, USP

Other means of identification

Synonyms: 3H-1,2,4-Triazol-3-one,
 4-(4-(4-(4-((2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl)methoxy)phenyl)-1-piperazinyl)phenyl)-2,4-dihydro-2-(1-methylpropyl)-;
 Oriconazole

CAS #: 84625-61-6
RTECS # XZ5481000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Medication. Antifungal.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
 14422 South San Pedro St.
 Gardena, CA 90248
 (310) 516-8000

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300

Contact Person: Martin LaBenz (West Coast)

Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3

Label elements

Warning

Hazard statements
 Harmful if swallowed

Causes skin irritation
Causes serious eye irritation
May cause respiratory irritation



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Avoid breathing dust/fume/gas/mist/vapors/spray
Wear protective gloves
Wear eye/face protection
Use only outdoors or in a well-ventilated area

Precautionary Statements - Response

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
IF ON SKIN: Wash with plenty of water
If skin irritation occurs: Get medical advice/attention
Take off contaminated clothing and wash it before reuse
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
Rinse mouth

Precautionary Statements - Storage

Store in a well-ventilated place. Keep container tightly closed
Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Itraconazole	84625-61-6	100

4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.

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Eye Contact: Flush eyes with water for 15 minutes. Get medical attention.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms

- Irritating to eyes and skin
- Skin rash
- Irritating to respiratory system
- Upset stomach
- May cause stomach cramping
- Nausea
- Vomiting
- May cause diarrhea
- Central nervous system effects
- May affect the liver
- Jaundice
- Dark urine
- May cause loss of appetite
- May affect the cardiovascular system
- Hypertension
- Heart failure
- Hypokalemia
- Dyspnea (Shortness of breath and difficulty breathing)

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Dry chemical. Carbon dioxide (CO₂). Water spray mist or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon Monoxide, Carbon Dioxide. Nitrogen Oxides. Hydrogen Chloride Gas.

Specific hazards: May be combustible at high temperatures.

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protective equipment. Avoid dust formation. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not ingest. Do not breathe vapors/dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Protect from light. Sensitive to light. Store in light-resistant containers. Store away from incompatible materials.

Incompatible Materials:

Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Itraconazole	84625-61-6	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Itraconazole	84625-61-6	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Itraconazole	84625-61-6	None	None

Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Goggles

Skin and body protection: Long sleeved clothing
Chemical resistant apron
Gloves

Respiratory protection: Wear respirator with dust filter. Be sure to use an approved/certified respirator or equivalent.

Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Powder.	Color: White. Off-white. Slightly yellow.
Odor: None.	Taste No information available.	Formula: C35-H38-Cl2-N8-O4
Molecular/Formula weight: 705.63	Flammability: No information available	Flashpoint (°C/°F): No information available.
Flash Point Tested according to: Not applicable	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): 163-170 °C/325.4-338 °F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: No information available	pH: No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water):	

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No information available

Viscosity:
No information available

Miscibility:
No information available

Solubility:
Practically insoluble in water

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Incompatible materials. Exposure to light.

Incompatible Materials: Oxidizing agents

Hazardous decomposition products: Carbon monoxide. Carbon dioxide. Hydrogen chloride gas. Nitrogen oxides (NO_x).

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Ingestion. Inhalation.

Acute Toxicity

Component Information

Itraconazole	
CAS-No.	84625-61-6

LD50/oral/rat = > 320 mg/kg Oral LD50 Rat
LD50/oral/mouse = No information available
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = > 320 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = No information available

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LD50/dermal/rabbit**VALUE-Acute Tox Dermal** = No information available**LD50/dermal/rat****VALUE -Acute Tox Dermal** = No information available**LC50/inhalation/rat****VALUE-Vapor** = No information available**VALUE-Gas** = No information available**VALUE-Dust/Mist** = No information available**LC50/Inhalation/mouse****VALUE-Vapor** = No information available**VALUE - Gas** = No information available**VALUE - Dust/Mist** = No information available**Symptoms****Skin Contact:** Causes skin irritation. Moderately irritating to the skin.**Eye Contact:** Causes eye irritation. Moderately irritating to the eyes.**Inhalation** Irritating to respiratory system.**Ingestion** Harmful if swallowed. May cause digestive (gastrointestinal) tract irritation. May cause upset stomach. May cause loss of appetite. May cause nausea. May cause vomiting. May cause diarrhea. May cause abdominal discomfort. May cause stomach cramping. May affect the liver and cause jaundice, a yellowing of the skin and/or eyes. May cause skin rash, redness or itching. It may affect cardiovascular system (hypertension). May affect the cardiovascular system (palpitations). May affect the cardiovascular system (tachycardia). May cause hypokalemia. May cause swelling of the ankles, feet, legs. May affect behavior/central nervous system (dizziness, headache). May affect behavior/central nervous system (fatigue, weakness). May affect behavior/central nervous system (tiredness). May affect behavior/central nervous system (confusion). May cause coughing. May affect respiration (shortness of breath).**Aspiration hazard** No information available.**Delayed and immediate effects as well as chronic effects from short and long-term exposure****Chronic Toxicity** Prolonged or repeated ingestion may affect the liver (jaundice, liver function tests impaired). Prolonged or repeated ingestion may affect the liver (Hepatitis, jaundice). Prolonged or repeated ingestion may affect the blood (changes in serum composition). Prolonged or repeated ingestion may affect the adrenal gland. Prolonged or repeated ingestion may affect the heart (cardiomyopathy including infarction). Chronic exposure may affect the peripheral nervous system (peripheral neuropathy with muscle weakness, paresthesia - a sensation of tingling, pricking, or numbness of the skin (known as the feeling of "pins and needles) generally of the hands and feet (extremities). Prolonged or repeated ingestion may cause decreased libido, enlarged breasts in men. Prolonged or repeated ingestion may affect behavior/central nervous system.**Sensitization:** May cause sensitization by skin contact.**Mutagenic Effects:** No information available

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Itraconazole	84625-61-6	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity No data is available

Reproductive Effects: No information available

Developmental Effects: Itraconazole interfered with embryo development in experimental animals at maternally toxic dose levels by a mechanism that appeared not to be relevant to humans

Teratogenic Effects: There are no adequate and well-controlled studies in humans

No information available

Specific Target Organ Toxicity

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility: No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Itraconazole	84625-61-6	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Class No information available
Packing group: No information available
Emergency Response Guide Number No information available
Marine Pollutant No data available
DOT RQ (lbs): No information available
Special Provisions No Information available
Symbol(s): No information available
Description: No information available

TDG (Canada)

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant No Information available
Description: No information available

ADR

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: No information available

IMO / IMDG

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant No information available

RID

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

ICAO

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

IATA

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

ERG Code: No information available
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Itraconazole	84625-61-6	Not Listed	Not present	Not present	Not present	Not present	Present	Not present

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Itraconazole	84625-61-6	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Itraconazole	84625-61-6	None	None	None	None	None

U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Itraconazole	84625-61-6	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information: The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

WHMIS 1988 Hazard Class

D2B Toxic materials
D1B Toxic materials

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS

Product code: I2662

Product name: ITRACONAZOLE,
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contains all of the information required by the CPR.

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Itraconazole	84625-61-6	Not Listed	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Itraconazole	84625-61-6	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Itraconazole	84625-61-6	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Itraconazole	84625-61-6	

EU - CLP (1272/2008)

R-phrase(s)

R22 - Harmful if swallowed.

R36/37/38 - Irritating to eyes, respiratory system and skin.

S -phrase(s)

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S46 - If swallowed, seek medical advice immediately and show this container or label.

S37/39 - Wear suitable gloves and eye/face protection.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Itraconazole	84625-61-6		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

Xi - Irritant.

Xn - Harmful.

Xi



Xn



16. OTHER INFORMATION

Preparation Date: 3/09/2016
Revision Date: 6/19/2018
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or

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End of Safety Data Sheet